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REMARKS

Claims 14 to 37 are now pending.

Reconsideration is respectfully requested based on the following.

With respect to paragraph three (3) of the Office Action, claims 14 to 37 were rejected under the first paragraph of 35 U.S.C. § 112 as to the enablement requirement.

As regards the enablement rejections, it is respectfully submitted that the Office Action's assertions and arguments presented do not reflect the standard for determining whether a patent application complies with the enablement requirement that the specification describe how to make and use the invention -- which is defined by the claims. (See M.P.E.P. § 2164). The Supreme Court established the appropriate standard as whether any experimentation for practicing the invention was undue or unreasonable. (See M.P.E.P. § 2164.01 (citing Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916); In re Wands, 858 F.2d. 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed Cir. 1988))). Thus, it is axiomatic that the enablement test is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (See id. (citing United States v. Teletronics, Inc., 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988))).

The Federal Circuit has made clear that there are many factors to be considered in determining whether a specification satisfies the enablement requirement, and that these factors include but are not limited to the following: the breadth of the claims; the nature of the invention; the state of the prior art; the level of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the disclosure. (See id. (citing In re Wands, 858 F.2d at 737, 8 U.S.P.Q.2d at 1404 and 1407)). In this regard, the Federal Circuit has also stated that it is "improper to conclude that a disclosure is not enabling based on an analysis of only one of the above factors," and that the examiner's analysis must therefore "consider all the evidence related to each of these factors" so that any nonenablement conclusion "must be based on the evidence as a whole." (See M.P.E.P. § 2164.01).

Also, an examiner bears the initial burden of establishing why the "scope of protection provided by a claim is not adequately enabled by the disclosure." (See id. (citing In re Wright, 999 F.2d 1557, 1562, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993))).

Accordingly, a specification that teaches the manner and process of making and using an

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invention in terms that correspond in scope to those used in describing and defining the claimed subject matter complies with the enablement requirement. (See id.).

In contrast to the above, however, it is respectfully submitted that the Office Action's unsupported assertions simply do not concern — as they must under the law — whether the present application enables a person having ordinary skill in the art to practice the claimed subject matter of the claims without undue experimentation — which it plainly does, as would be understood by a person having ordinary skill in the art in view of the disclosure of the present application, including the specification. In short, the Office Action's assertions are merely conclusory and do not address the issue of whether one having ordinary skill would have to unduly experiment to practice the claimed subject matter of the rejected claims — a proposition for which the Office bears the burden of proving a prima facie case as to the rejected claims.

In this regard, to properly establish enablement or non-enablement, the Office must make use of proper evidence, sound scientific reasoning and the established law. In the case of Ex Parte Reese, 40 U.S.P.Q.2d 1221 (Bd. Pat. App. & Int. 1996), a patent examiner rejected (under the first paragraph of section 112) application claims because they were based on an assertedly non-enabling disclosure, and was promptly reversed because the rejection was based only on the examiner's subjective belief that the specification was not enabling as to the claims. In particular, the examiner's subjective belief was simply not supported by any "evidence or sound scientific reasoning" and therefore ignored recent case law — which makes plain that an examiner (and not an applicant) bears the burden of persuasion on an enablement rejection.

More particularly, the examiner in <u>Ex parte Reese</u> was reversed because the rejection had only been based on a conclusory statement that the specification did not contain a sufficiently explicit disclosure to enable a person to practice the claimed invention without exercising undue experimentation — which the Board found to be merely a conclusory statement that only reflected the subjective and unsupported beliefs of a particular examiner and that was not supported by any proper evidence, facts or scientific reasoning. (See <u>id.</u>). Moreover, the Board made clear that it is "incumbent upon the Patent Office . . . to back up assertions of its own with acceptable evidence," and also made clear that "[where an] examiner's 'Response to Argument' is not supported by evidence, facts or sound scientific reasoning, [then an] examiner has not established a *prima facie* case of lack of enablement under 35 U.S.C. § 112, first paragraph." (See <u>id.</u> at 1222 & 1223; italics in original).

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In the present case, the Office Action has not even alleged in a conclusory way that undue experimentation would be required. Moreover, even as to the assertions as presented, the present application plainly discloses how to use the subject matter of the rejected claims, as explained above.

It is therefore respectfully requested that the enablement rejections be withdrawn in view of the foregoing.

It is therefore respectfully submitted that all of claims 14 to 37 are allowable.

Conclusion

In view of the foregoing, it is believed that the rejections have been obviated, and that claims 14 to 37 are allowable. It is therefore respectfully requested that the rejections be withdrawn, and that the present application issue as early as possible.

Respectfully submitted

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